

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF OHIO  
WESTERN DIVISION

TIFFANI BROWN,

Plaintiff,

Case No. 3:12 oe 40003

-vs-

MEMORANDUM OPINION

JANSSEN PHARMACEUTICALS, INC.,  
et al.,

Defendant.

KATZ, J.

Plaintiff Tiffani Brown sued Defendants when she experienced bilateral pulmonary emboli after using Defendants' Ortho Evra® birth control patch. Plaintiff advances Tennessee state law claims for failure to warn, as well as sundry other tort claims. Defendants have moved for summary judgment as to Plaintiff's failure to warn claims, as well as for judgment on the pleadings as to the remainder of Plaintiff's claims. For the reasons that follow, Defendants' motion for summary judgment is granted, and Defendants' motion for judgment on the pleadings is granted in part and denied in part.

**I. Background**

Plaintiff was first prescribed the Ortho Evra® birth control patch in December 2008, and she continued using Ortho Evra® through February 2010. Plaintiff received the prescription from her gynecologist, William Fitts, M.D., at the Dyersburg General Hospital in Dyersburg, Tennessee. Dr. Fitts is a licensed medical doctor and is Board certified in obstetrics and gynecology. The record reflects that at the time Dr. Fitts prescribed the Ortho Evra®, he was aware that Ortho Evra® exposes users to increased levels of estrogen, and that such increased exposure increases the risk of blood clots. Moreover, Dr. Fitts testified that notwithstanding these

risks, he believed Ortho Evra® was a reasonably safe method of birth control for Plaintiff, and further believed that the risks to Plaintiff were outweighed by the drug's benefits.

In February 2010, Plaintiff suffered bilateral pulmonary emboli, allegedly as a result of using Ortho Evra®. Plaintiff subsequently commenced this action in the Superior Court of California for Los Angeles County, adopting the Master Complaint for California's *In re: Ortho Evra® Litigation* Judicial Council Coordination Proceeding. Thereafter, the case was removed to the Central District of California and transferred to this Court's Ortho Evra® multidistrict litigation docket. Defendants then filed the instant motion for summary judgment and judgment on the pleadings.

## **II. Legal Standards**

### **A. Summary Judgment**

Summary judgment is appropriate where "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). The moving party bears the initial responsibility of "informing the district court of the basis for its motion, and identifying those portions of 'the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any,' which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323, 106 S. Ct. 2548, 2553, 91 L. Ed. 2d 265 (1986). The movant may meet this burden by demonstrating the absence of evidence supporting one or more essential elements of the non-movant's claim. *Id.* at 323-25. Once the movant meets this burden, the opposing party "must set forth specific facts showing that there is a genuine issue for trial."

*Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250, 106 S. Ct. 2505, 2541, 91 L. Ed. 2d 202 (1986) (quoting FED. R. CIV. P. 56(e)).

Once the burden of production has so shifted, the party opposing summary judgment cannot rest on its pleadings or merely reassert its previous allegations. It is not sufficient “simply [to] show that there is some metaphysical doubt as to the material facts.” *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586, 106 S. Ct. 1348, 1356, 89 L. Ed. 2d 538 (1986). Rather, Rule 56(e) “requires the nonmoving party to go beyond the pleadings” and present some type of evidentiary material in support of its position. *Celotex*, 477 U.S. at 324, 106 S. Ct. at 2553; see also *Harris v. General Motors Corp.*, 201 F.3d 800, 802 (6th Cir. 2000). Summary judgment must be entered “against a party who fails to make a showing sufficient to establish the existence of an element essential to that party’s case, and on which that party will bear the burden of proof at trial.” *Celotex*, 477 U.S. at 322, 106 S. Ct. at 2552.

“In considering a motion for summary judgment, the Court must view the facts and draw all reasonable inferences therefrom in a light most favorable to the nonmoving party.” *Williams v. Belknap*, 154 F. Supp. 2d 1069, 1071 (E.D. Mich. 2001) (citing *60 Ivy Street Corp. v. Alexander*, 822 F.2d 1432, 1435 (6th Cir. 1987)). However, “at the summary judgment stage the judge’s function is not himself to weigh the evidence and determine the truth of the matter,” *Wiley v. U.S.*, 20 F.3d 222, 227 (6th Cir. 1994) (quoting *Anderson*, 477 U.S. at 249); therefore, “[t]he Court is not required or permitted . . . to judge the evidence or make findings of fact.” *Williams*, 154 F. Supp. 2d at 1071. The purpose of summary judgment “is not to resolve factual issues, but to determine if there are genuine issues of fact to be tried.” *Abercrombie & Fitch Stores, Inc. v. Am. Eagle Outfitters, Inc.*, 130 F. Supp. 2d 928, 930 (S.D. Ohio 1999). Ultimately,

this Court must determine “whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law.”

*Anderson*, 477 U.S. at 251-52; *see also Atchley v. RK Co.*, 224 F.3d 537, 539 (6th Cir. 2000).

#### **B. Judgment on the Pleadings**

The Court construes Plaintiff’s motion to dismiss as a Fed. R. Civ. P. 12(c) motion for judgment on the pleadings.

A Fed. R. Civ. P. 12(c) motion for judgment on the pleadings is analyzed under the same standard as a Fed. R. Civ. P. 12(b)(6) motion to dismiss. *Sensations, Inc. v. City of Grand Rapids*, 526 F.3d 291, 295 (6th Cir.2008). To defeat such a motion, the complaint must state sufficient facts, accepted as true, to state a claim “that is plausible on its face.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

In deciding the motion, the Court must accept as true all of the non-movant’s factual allegations. *Erickson v. Pardus*, 551 U.S. 89, 94 (2007); *Thurman v. Pfizer, Inc.*, 484 F.3d 855, 859 (6th Cir. 2013). The complaint “need not contain ‘detailed’ factual allegations, [but] its ‘factual allegations must be enough to raise a right to relief above the speculative level . . . .’” *Ass’n of Cleveland Fire Fighters v. City of Cleveland, Ohio*, 502 F.3d 545, 548 (6th Cir. 2007) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). Conclusory allegations and legal conclusions masquerading as factual allegations will not suffice. *Twombly*, 550 U.S. at 555 (holding that a complaint must contain more than “a formulaic recitation of the elements of the cause of action”).

### III. Discussion

#### A. Summary Judgment on Failure to Warn

Defendants move for summary judgment on Plaintiff's failure to warn claims, arguing the claims are barred by Tennessee's learned intermediary doctrine. *See Pittman v. Upjohn Co.*, 890 S.W.2d 425, 429 (Tenn. 1994) (discussing learned intermediary doctrine). "In Tennessee, the learned intermediary doctrine is applicable in failure to warn suits where a physician is the intermediary between a defendant pharmaceutical or other medical product manufacturer and an injured patient." *Nye v. Bayer Cropscience, Inc.*, 347 S.W.3d 686, 701 (Tenn. 2011) (citations omitted). The doctrine provides that "a pharmaceutical manufacturer can discharge its duty to warn by providing the physician with adequate warnings of the drug's risks." *Id.* (citing *Pittman*, 890 S.W.2d at 429).

Here, Defendants provided adequate warnings sufficient to discharge their duty to warn Plaintiff's prescribing physician, Dr. Fitts. *Pittman, supra*, is instructive. In that case, the Tennessee Supreme Court explained that prescription drug warnings are adequate:

when they contain a full and complete disclosure of the potential adverse reactions to the drug. . . . Among the criteria for determining the adequacy of a warning are:

1. the warning must adequately indicate the scope of the danger; 2. the warning must reasonably communicate the extent or seriousness of the harm that could result from the misuse of the drug; 3. the physical aspects of the warning must be adequate to alert a reasonably prudent person to the danger; 4. a simple directive warning may be inadequate when it fails to indicate the consequences that might result from failure to follow it and, ... 5. the means to convey the warning must be adequate.

*Pittman*, 930 S.W.2d at 429 (quoting *Serna v. Roche Labs.*, 684 P.2d 1187, 1189 (N.M.App. 1984)). Under this framework, the *Pittman* court found that the drug warning at issue in that case

was adequate as a matter of law because the instructions were accurate, unambiguous, and provided extensive information specifically warning of the adverse events suffered. *See id.* at 429-31 (finding warning adequate as a matter of law); *id.* at 429-30 (though adequacy of warning is usually question of fact, it becomes question of law “when the instructions are accurate and unambiguous.”). Similarly, in the instant matter, Defendants’ October 2008 Ortho Evra® package insert, which was in effect at the time Dr. Fitts prescribed Ortho Evra® to Plaintiff, provided specific warnings of the exact adverse events suffered by Plaintiff; namely, the package insert warned that Ortho Evra®’s increased levels of estrogen can increase the risk of developing blood clots that may travel to the lungs. Moreover, Dr. Fitts testified that at the time he prescribed Ortho Evra® to Plaintiff, he was aware of the drug’s increased levels of estrogen, and that such increased estrogen raises the risk of blood clots. Further, Dr. Fitts testified that notwithstanding these risks, he believed Ortho Evra® was a reasonably safe method of birth control for Plaintiff, and believed that the risks to Plaintiff were outweighed by the drug’s benefits. Thus, the learned intermediary doctrine bars Plaintiff’s failure to warn claims, and Defendants’ motion for summary judgment will be granted.

#### **B. Judgment on the Pleadings as to Non-Failure to Warn Claims**

Defendants move for judgment on the pleadings as to Plaintiff’s claims for manufacturing defect, negligence, breach of warranties and fraud.

At the outset, the Court notes that Defendants’ reply brief claims that since Plaintiff contends that all theories of recovery are predicated on Defendants’ alleged failure to warn, the learned intermediary analysis, *supra*, requires judgment on the pleadings on all claims, even on Plaintiff’s non-failure to warn claims. Importantly, it is improper for Defendants to raise this issue

for the first time in their reply brief. *See Scottsdale Ins. Co. v. Flowers*, 513 F.3d 546, 553 (6th Cir. 2008) (explaining reply briefs allow moveant to reply to opposition's arguments, not raise new arguments in support of motion). In any event, Defendants do not provide the Court with any explanation or authority as to why non-failure to warn causes of action are barred by a doctrine designed to preclude failure to warn claims. Defendants' unsupported, passing assertion neither offers a meaningful analysis, nor a basis on which to grant judgment on the pleadings.

Defendants also move for judgment on the pleadings on grounds that Plaintiff's complaint contains insufficient factual allegations and therefore amounts to the sort of formulaic recitation of the elements precluded under *Twombly*, 550 U.S. at 555. Upon review, the Court finds Plaintiff's complaint is not violative of the Federal Rules' pleading standards. Rather, Plaintiff's complaint states sufficient factual matter to put Defendants on notice as to the nature of her claims, and to state claims that are plausible on their face. *See* Long Form Master Compl. for Judicial Council Coordinated Proceeding 4506, Doc. 1; *see also* Fed. R. Civ. P. 8(a) (pleading must contain short plain statement of claim showing pleader is entitled to relief); *Twombly*, 550 U.S. at 555 (Rule 8(a) requires that complaint contain sufficient factual matter to establish claim that is plausible on its face); *accord Iqbal*, 556 U.S. at 678. Further, Plaintiff pleads her fraud claim with sufficient particularity to satisfy Fed. R. Civ. P. 9(b)'s heightened pleading standard. As such, Defendants are not entitled to judgment on the pleadings on grounds that Plaintiff's complaint does not contain sufficient factual allegations.

Defendants also argue they are entitled to judgment on the pleadings as to Plaintiff's claims for breach of warranty because Plaintiff did not plead privity of contract with Defendants, as required by Tennessee's breach of warranty laws. Defendants are correct that in *Hargrove v.*

*Newsome*, 470 S.W.2d 348 (1971), the Tennessee Supreme Court explained that Tennessee’s Code requires privity for actions in warranty. *See id.* at 469-70 (explaining privity required for breach of warranty claims in product liability actions). Plaintiff’s complaint does not plead privity, and Defendants are therefore entitled to judgment on the pleadings as to Plaintiff’s claims for breach of implied warranty and breach of express warranty.

Further, Defendants argue they are entitled to judgment on the pleadings as to Plaintiff’s claims for violation of California Business and Professions Code §§ 17200 and 17500. Defendants argue that Plaintiff, a Tennessee resident, does not have standing to bring these claims under the California Business and Professions Code. Defendants are correct. As explained by *Norwest Mortgage, Inc. v. Superior Court*, 72 Cal. App. 4th 214, 222 (Cal. Ct. App. 1999), the Code does not regulate “claims of non-California residents arising from conduct occurring entirely outside of California.” Though Defendants raise this argument for the first time in their reply, *see Scottsdale*, 513 F.3d at 553 (movant may not raise argument for first time in reply), the issue of standing cannot be waived and it may be raised *sua sponte* by the Court. *Cnty. First Bank v. NCUA*, 41 F.3d 1050, 1053 (6th Cir. 1994). As such, the Court will enter judgment on the pleadings against Plaintiff’s claims for violation of California Business and Professions Code §§ 17200 and 17500.

#### **IV. Conclusion**

For the reasons stated herein, Defendants’ motion for summary judgment on Plaintiff’s failure to warn claims is granted. (Doc. 18). Defendants’ motion for judgment on the pleadings is granted as to Plaintiff’s breach of implied warranty claim, breach of express warranty claim, and



as to Plaintiff's claims for violation of Business and Professions Code §§ 17200 and 17500.

Defendants' motion for judgment on the pleadings is denied as to all other claims. (Doc. 18).

IT IS SO ORDERED.

S/ David A. Katz  
DAVID A. KATZ  
U. S. DISTRICT JUDGE